DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date

From Joseph C. Famulare, Director
Division of Manufacturing and Product Quality, HFD-320

Subject Multi-District Office Assignment

To See Attached List

HOSPITALS, NURSING HOMES, AND OTHER HEALTH CARE FACILITIES ASSESSMENT

The agency has received four reports of medical gas mix-ups occurring during the past 5 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facilities' oxygen supply system.

On April 6, 2001, the agency published its ***Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities [FDA PUBLIC HEALTH ADVISORY]*** which may be found at the following website: ***http://www.fda.gov/cder/guidance/4341fnl.htm.*** This guidance makes recommendations that will help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups, and is intended to alert these facilities to the hazards of medical gas mix-ups.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published its Sentinel Event Alert Issue 21 in July 2001 which is available at http://www.jcaho.org/index.htm. A Sentinel Event Alert identifies the most frequently occurring events, describes their common underlying causes, and suggests steps to prevent occurrences in the future. We expect hospitals, nursing homes, and other health care facilities to have steps in place to prevent medical gas mix-ups from occurring through the facility's distribution system. This expectation does not reside specifically within the CGMP, but rather with the

various state requirements as well as the JCAHO Standards. Further, the agency's regulatory authority over hospitals is limited. Therefore, we are looking to gather information through the facilities voluntarily cooperation with FDA.

We are requesting assessment visits to 285 hospitals, nursing homes, or other health care facilities across the country that provide medical gases through oxygen supply systems. The requested assessment will consist of a discussion with management and operators of the facilities regarding the guidance provided in the FDA Public Health Advisory, and an investigation about the conditions and practices in the facilities regarding employee training, and receipt, storage, connection, and monitoring of medical gas products. An assessment information form is provided and should be filled out during each assessment visit.

During the assessment, determine if the FDA Warning Poster is located where the connection of the large portable cryogenic containers occurs, and where the person responsible for assessing a correct connection may view it.

NOTE: Only health care facilities that receive large portable cryogenic containers, e.g. VGLs, PLCs, and/or GPs and connect these containers to oxygen supply systems are to be covered in this assignment. The fittings on the large portable cryogenic container should be observed to determine if these fittings have been permanently attached to the container by either silver brazening (welded) or by a device that is removable only by the manufacturer of the drug product. Investigators should also view the 360-degree wrap around label applied to these containers.

Facilities that have large permanent storage tanks residing on the outside of their premises are not included in this assignment, and should not be visited.

The operation should be reported into the data system as a domestic investigation under operation 13. The report should consist of a memorandum documenting the assessment visit (site identification, information source identification) and a completed assessment information form (See attachment).

No samples are to be collected.

Each District Office with an investigations unit (19 District Offices) should review their Official Establishment Inventory and select several large suppliers of medical gases that produce multiple gases. The district may choice to initiate a telephone call to each supplier or may choose to visit each one to obtain a listing of all health care facilities that are provided with large cryogenic containers. From this list, identify 15 hospitals, nursing homes, or other health care facilities having the medical gas systems as described above, and visit each designated health care facility to carry out the operation called for in this assignment.

We recommend investigators use these firms as "fall back assignments" while the investigator is out on other assignments, so that these identified health care facilities may be visited on route.

This assignment will have as its objectives:

- To raise the awareness of hospitals, nursing homes, and other health care facilities management and operators of the occurrences of medical gas errors in the connection of medical gases and possible conditions and practices which may contribute to or result in this type of medical error.

- To distribute educational materials, prepared by FDA and JCAHO, to reduce the incidence of improper connection of medical gases to supply lines in health care facilities. [FDA's Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities, FDA PUBLIC HEALTH ADVISORY, is at http://www.fda.gov/cder/guidance/4341fnl.htm. JCAHO's Event Alert Issue 21 in July 2001 at http://www.jcaho.org/index.htm.]

- To make a representative assessment of conditions and practices in the health care industry across the country related to medical gas delivery to health care facility patients.

- To determine whether the health care facilities have implemented the recommendations addressed in the Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities.

- To obtain information about past medical gas mix-ups that may have occurred in the last several years, and that were not reported.

Since these assessments are not CGMP inspections and consist of 1) a brief discussion with management and operators of the health care facility regarding the guidance provided in the above document, 2) the collection of information about the conditions and practices in the facility regarding the training, receipt, connection, and monitoring of medical gas products, and 3) observing the cryogenic container fittings, the 360-degree wrap around label, and the quarantine area, no FDA482s or 483s should be issued.

In the event that a visit finds an incorrect medical gas fitting, the proper health care official should be notified immediately. Report the findings to CDER on the same day to discuss what type of investigation should be performed at the supplier to determine if this is an isolated occurrence, or if the supplier routinely distributes large portable cryogenic containers in this manner.

If you should have any questions concerning this assessment, please contact the

Center for Drug Evaluation and Research, Duane S. Sylvia, Division of Manufacturing & Product Quality (HFD-320), Telephone: (301) 827-9040 Fax: (301) 827-8907

For educational materials, such as posters or stickers contact, Cynthia P. Fitzpatrick, Public Affairs Liaison, FDA/CDER/OTCOM/DPA, 5600 Fishers Lane, Room 12B-31, Rockville, MD 20857, 301-827-1672 Fax 301-827-3055

The Division of Manufacturing and Product Quality (DMPQ) HFD-320, 11919 Rockville Pike, Rockville, Maryland 20852 will receive the information collected, prepare an evaluation of the data, and issue a report with further actions recommended as needed.

The DMPQ evaluation will address the effectiveness of the guidance published by the agency and outside organizations, with the intent to provide additional guidance if warranted by the findings and to ascertain whether health care organizations have promptly implemented adequate written operating procedures, and training.

The evaluation will also be used to assess the current industry practice of permanently attaching the cryogenic container fittings and the application of a 360-degree wrap around label.

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Joseph C. Famulare

Date: _____

To: Duane S. Sylvia, HFD-320

Subject: Medical Gas Errors Assessment Report

Name and address of the facility visited: _____

Contact Person and their telephone number: _____

Name and address of their supplier: _____

INFORMATION FROM MANAGEMENT

- Is the facility aware of FDA's Guidance to Hospitals issued April 6, 2001?
  Yes_____ No_____

- How did the facility become aware of it?
  *Internet_____
  *Direct Mailing_____
  *JCAHO Sentinel Event Alert_____
  *Their supplier_____
  *Other sources_____

- Does the facility have Standard Operating Procedures (SOP) addressing:

  *Training in medical gas delivery and hookup?
  Yes_____ No_____

  *Label examination of the medical gas?
  Yes_____ No_____

  *Separate quarantine areas for medical & industrial grade product?
  Yes_____ No_____

- Does the facility have and use industrial gases?
  Yes_____ No_____

- If yes, what are they used for
  *Running tools_____
  *Human procedures such as laproscopy_____
  *Others_____

- Is the facility aware that only medical gases should be used for contact with the human body, since industrial gases may contain toxic contaminants?
  Yes_____ No_____

- Does the facility SOP include a confirmatory inspection to assure the proper connection of delivered gases?
  Yes_____ No_____

- Who is responsible for this task? (Please check one)
  *Respiratory therapist staff_____
  *Nursing staff_____
  *Pharmacy staff_____
  *Maintenance staff_____
  *Other_____

- Does the facility document the post-confirmatory inspection?
  Yes_____ No_____

- Is the facility aware of reporting adverse events to FDA whether or not a death or injury is involved?
  Yes_____ No_____

VISUAL CONFIRMATION

- Are the fittings on the large portable cryogenic containers the facility is currently using permanently attached?
  Yes_____ No_____

- What method is used to permanently attach the fitting to the container?
  Silver brazen_____
  Permanent device____

- Do the containers bear a 360-degree wrap around label with the name of the medical gas repeated around the entire label?
  Yes_____ No_____

- Has the facility posted FDA's Warning Poster?
  Yes_____ No_____

If yes, where is the poster located? _____

- Does the facility have separate storage areas for medical & industrial gases?
  Yes_____ No_____

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